

Meeting date: 5 May 2005

Open Govt. Status: Fully Open

Type of paper: For debate

Paper File Ref:

Exemptions:

WATCH COMMITTEE

Styrene

Issue

1. (i) How the current standing of the EU ESR (Existing Substances Regulation, 793/93) toxicity profile for styrene compares with the current UK occupational risk management position for this substance; and (ii) how to assess the effects on colour discrimination reported to arise from occupational exposure to styrene and other organic solvents.

Timing Considerations

2. No crucial timing issues, although during 2005 EU ESR discussions on styrene will continue.

Recommendation

3. WATCH is invited to consider the issues noted in this cover paper, supplemented by the annexes; and to respond to the actions in paragraph 20.

Background

4. With the introduction of the new UK Occupational Exposure Limit framework (April 2005), styrene has Workplace Exposure Limits (WELs) of 100 ppm (8-hour TWA) and 250 ppm (15-minute reference period). These limit values have been taken directly from the Maximum Exposure Limits (MELs) for styrene that applied before this new framework.
5. These numerical UK limit values for styrene were established about 20 years ago, first as pre-COSHH Control Limits, which then became MELs with the introduction of COSHH. The original basis for establishing this *type* of exposure limit was that the numerical values represented the lowest levels of exposure deemed to be reasonably practicable for the whole of UK industry to achieve, but there remained concerns that ill-health effects (irritation and acute central nervous system disturbance) could occur with such exposures.
6. There have been significant developments in the intervening years, including the generation and publication of a large amount of new toxicity information on styrene. Styrene was selected for review, with the UK as rapporteur, in the first priority list of substances for risk assessment under the Existing Substances Regulation (ESR). During its genesis and consideration within the EU ESR process, WATCH has seen draft versions of the human health aspects of the ESR risk assessment document, first in May 1995 and then an amended version in January 2001 (WATCH/05/2001). Toxicological data has continued to appear and EU-wide debate within the ESR context has continued, most recently at the ESR "Technical Meeting" in March of this year.
7. Against this background, there are also indications that it might now be reasonably practicable to control exposure to styrene more stringently than was previously the case. Hence, alongside the introduction of the new "WEL" framework, the UK occupational risk management position for styrene has been identified for review (one of 15 such cases of substances that formerly had MEL status).

Argument

8. As indicated in paragraph 6, the most recent discussion of the toxicological profile of styrene in the context of ESR was in March 2005. The outcome of this discussion is that most of the toxicological profile of styrene has now been agreed among EU Member States. **A summary of this agreed toxicological profile, as presented in the current draft of the ESR Risk Assessment Report, is presented at Annex 1 to this paper.** The aspects not yet agreed are the sections and positions reached on mutagenicity and carcinogenicity – see paragraph 15 below. For the reasons given there, the text of Annex 1 relating to mutagenicity and carcinogenicity has been put into a box and WATCH is asked **not** to consider these two endpoints at this May WATCH meeting.

9. The key health effects that have been identified and on which agreed positions have now been taken are acute toxicity (CNS depression) skin, eye and respiratory tract irritation and repeated dose toxicity.

10. For acute toxicity, a NOAEL (or NOAEC in ESR terminology) of 100 ppm has been identified in humans, with evidence of CNS depression at higher acute exposure levels. NOAELs (NOAECs) of about 200 ppm have been identified for eye and respiratory tract irritation in humans exposed to styrene vapour.

11. In relation to repeated dose toxicity, in animal studies ototoxicity has been identified as the most significant effect; a NOAEL (NOAEC) of 200 ppm for 13 weeks' exposure in rats has been observed.

12. In humans repeatedly exposed to styrene, there remains an unclear and somewhat contentious picture surrounding the concept that repeated exposure to styrene (and other organic solvents) can result in long-term effects on the nervous system. This territory has been explored intensely by WATCH in the past, in relation to organic solvents in general and also (particularly at the January 2001 WATCH meeting) specifically to styrene. Nevertheless, an agreed position has emerged in EU ESR discussions, reflected in a short paragraph on page 6 of Annex 1, that:

“the crucial issue in relation to the impact of styrene on the nervous system is the need to avoid **acute** CNS depressant effects and associated symptomatology”

In this respect the position described in paragraph 10 is crucial.

13. Also during the EU ESR discussion, Member States paid great attention to the body of evidence indicating an effect of styrene on colour discrimination. The discussion focused on the health significance of this effect and on its risk implications. With the exception of one Member State, it was agreed that the slight impairment in colour vision reported with repeated exposures in the vicinity of 50 ppm (8h TWA) should not be considered as an adverse health outcome of styrene exposure. Member States concluded that this exposure value (50 ppm) should be considered as a no-adverse-effect level in relation to this phenomenon.

14. During 2003 HSE undertook a review of the literature on the effects of organic solvents on colour discrimination, culminating in the publication of a paper attached here as Annex 2. **The opinion of WATCH on the views expressed in the Annex 2 paper and on how to accommodate such data in assessing the hazards and risks to health of styrene and possibly other organic solvents is one of the Actions requested of WATCH.**

15. **Mutagenicity and carcinogenicity:** In relation to assessing the mutagenic and carcinogenic potential of styrene, the data and their interpretation has always been complex and, in the context of EU ESR discussions, disputed. The UK, as rapporteur, has repeatedly expressed the opinion that there is no convincing evidence that styrene possesses significant mutagenic or carcinogenic potential in relation to human health. Other Member States have expressed a range of opinions. Recently, a component part of the UK ESR regulatory

structure has sought the expert opinion of members of the Dept of Health/Food Standards Agency "Committee on Mutagenicity" (CoM). Pending this opinion and final resolution of an EU position on these toxicological endpoints for styrene, WATCH is asked to set aside any mutagenicity/carcinogenicity considerations for this May 2005 WATCH meeting.

16. In relation to all other aspects of the toxicological profile of styrene presented at Annex 1, the question arises as to how well this profile sits alongside the new WELs of 100 ppm (8h TWA) and 250 ppm (STEL) for styrene. **This is one of the questions now put to WATCH.**

Link to HSC Strategy

17. The basis for debating these issues emanates from HSE's work as part of the UK competent authority for ESR – an area of "mandatory" responsibilities within HSE's chemicals agenda.

Consultation

18. No wider consultation on this paper beyond HSE has been undertaken at this stage.

European Context

19. Styrene is a "first priority list substance" under the Existing Substances Regulation (ESR).

Action

20. WATCH is asked to consider the issues in this paper and to address how:

- (i) the current standing of the EU ESR (Existing Substances Regulation, 793/93) toxicity profile for styrene compares with the current UK occupational risk management position for this substance; and
- (ii) to assess the effects on colour discrimination reported to arise from occupational exposure to styrene and other organic solvents.

Contact:

Nicola Gregg
WATCH Secretariat

References / Attachments

- Annex 1 Summary of toxicological profile of styrene (as in the ESR Risk Assessment Report)
- Annex 2 R.B.Lomax, P. Ridgway and M.Meldrum. Does Occupational Exposure to Organic Solvents affect Colour Discrimination? *Toxicol Rev* 2004; 23 (2): 91-121.